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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,585	10/18/2003	Deanna Jean Nelson	BLS21102	2265

7590 09/13/2005

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104 Tasman Court  
Cary, NC 27513

EXAMINER
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WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/688,585	<b>Applicant(s)</b> NELSON, DEANNA JEAN	
	<b>Examiner</b> Everett White	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 and 11 is/are allowed.
- 6) ☒ Claim(s) 1-7,9,10 and 13-18 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### *Claim Objections*

1. Claims 1 and 12 are objected to because of the following informalities: In Claim 1, last 2 lines, the term "amides" is listed twice for the description of the "L group". This occurrence is also set forth in Claim 12, lines 9 and 11. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
3. Claims 1-5, 7, 9, 10 and 12-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claims 1, 2, 10 and 13-16, the metes and bounds of the term "sugar residue" cannot be determined which renders the claims indefinite. The term "sugar residue" should be changed to - - sugar - -. The term "sugar residue" in dependent Claims 3-5 should also be changed to - - sugar - - in order to comply with proper antecedent basis. This rejection in Claims 1, 2, 10 and 13-16 can also be over come by clarifying in these claims what is meant by the term "sugar residue".

In Claims 1, 9 and 12-16, the "Z" symbol is described by properties. This functional description makes it difficult to determine the identity of the Z moiety, which renders Claims 1, 9, and 12-16 vague and indefinite.

Claim 10 recites a process step that involves alkylating the amino group of 5-aminosalicylic acid with a reducing sugar. However, the term "alkylating" refers to the substitution of an alkyl group for a hydrogen atom in a cyclic compound. There is no indication in the instantly claimed procedure that an alkyl group is being substituted since the reactants are a sugar and an amino group.

In Claims 14 and 15, the metes and bounds of the text "prophylactically or interventionally treating a potential or developed condition or disease state in a human

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or non-human mammalian subject” cannot be determined which renders the claims indefinite. Claims 14 and 15 fail to set forth what’s being treated. The phrases “potential or developed condition” and “disease state” lack meanings absent further description of what condition or disease state the claims are referring to.

In Claims 17 and 18, the metes and bounds of the term “5-amino acid derivative” cannot be determined since Claims 17 and 18 do not clarify or give a detail description of the term “5-amino acid derivative”.

Claims 7 and 9 are also rejected since these claims are dependent upon Claim 1 and do not clarify the error disclosed for the above rejection of Claim 1.

### ***Claim Rejections - 35 USC § 102***

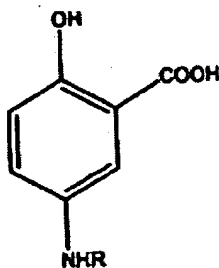
4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 5, 6, 13, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Tjoernelund et al (*Journal of Chromatography*, “Stability of 5-Aminosalicylic Acid and its Metabolites in Plasma at -20°C: Formation of N-β-D-Glucopyranosyl-5-Aminosalicylic Acid”, 1991, Vol. 570, No. 1, pp. 224-228)

Applicant claims a therapeutic 5-aminosalicylic acid derivative composition having the general formula:



wherein R is a sugar residue; a poly(ethylene glycol) chain-containing residue having the general formula  $-\text{CH}_2\text{CH}_2\text{CH}_2-(\text{CH}_2\text{CH}_2\text{O})_n-\text{R}_1$ ,  $\text{R}_1$  is H or a linear or branched

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lower alkyl group having from one to about 6 carbons, and n is a positive integer from about 3 to about 100; or a poly(ethylene glycol) chain-containing tether having the general formula  $-\text{CH}_2-(\text{CH}_2 \text{CH}_2\text{O})_n-(\text{CH}_2)_m-\text{Z}$ , in which n is a positive integer from about 3 to about 100, m is 2, 3, or 4, and Z is a pharmacologically active moiety having a molecular weight that is less than about 1000 Daltons that is covalently joined to the distal terminus of said poly(ethylene glycol) chain by a linker group L that is selected from the group consisting of carboxylic acid esters and amides, carbamates, phosphate esters, phosphinate esters, and sulfate and sulfonate esters and amides. Additional limitations in the dependent claims include specific type of sugar residue. It is noted that Claims 13, 17 and 18 are in the form of product-by-process claims. The Office considers product-by-process claims as product claims.

The Tjoernelund et al reference discloses the compound N- $\beta$ -D-glucopyranosyl-5-aminosalicylic acid being formed in plasma samples (see abstract), which suggests that the 5-aminosalicylic acid derivative composition of the formula disclosed in Claim 1 is anticipated by the Tjoernelund et al reference when R in the formula of instant Claim 1 represents a sugar residue, a 1-deoxymonosaccharide, or 1-deoxyglucose. Claims 13, 17 and 18 set forth the intended use of the product. Applicants are reminded that a difference in intended use cannot render a claimed composition novel. Note *In re Tuominen*, 213 USPQ 89 (CCPA, 1982); *In re Pearson*, 494 F.2d 1399; 181 USPQ 641 (CCPA, 1974); and *In re Hack* 114 USPQ 161.

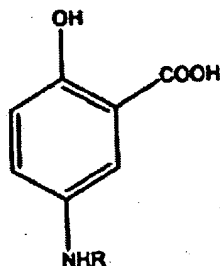
#### ***Reference Further Showing the State of the Art***

6. The Tjoernelund et al reference (*Xenobiotica*, "New Metabolites of the Drug 5-Aminosalicylic Acid I: N- $\beta$ -D-Glucopyranosyl-5-Aminosalicylic Acid", 1989, Vol. 19, No. 8, pp. 891-899), which also discloses N- $\beta$ -D-glucopyranosyl-5-aminosalicylic acid, is cited to further show the state of the art.

#### ***Allowable Subject Matter***

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7. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach or fairly suggest a therapeutic 5-aminosalicylic acid derivative composition having the general formula.



wherein R is a poly(ethylene glycol) chain-containing residue having the general formula  $-\text{CH}_2\text{CH}_2\text{CH}_2-(\text{CH}_2\text{CH}_2\text{O})_n-\text{R}_1$ ,  $\text{R}_1$  is H or a linear or branched lower alkyl group having from one to about 6 carbons, and  $n$  is a positive integer from about 3 to about 20.

### **Summary**

8. Claims 8 and 11 are allowed; Claims 1-7, 9, 10 and 12-18 are rejected.

### **Examiner's Telephone Number, Fax Number, and Other Information**

9. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for this Group is (571) 273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



E. White



James O. Wilson  
Supervisory Primary Examiner  
**Technology Center 1600**